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R.J. REYNOLDS TOBACCO COMPANY

Re: Strategic and Tactical Considerations Concerning Ingredients

I. STRATEGIC OBJECTIVES

Some plaintiffs in the smoking and health litigation are pursuing claims -- or at least discovery -- regarding certain cigarette ingredients (e.g., casing materials, glues, adhesives, paper, humectants, and flavorings). Although the ostensible purpose of the ingredients issue would be to establish some or all of the ingredients as a contributing cause of the plaintiff's disease, the actual purpose appears to be to use ingredients as an example of alleged misconduct by the industry. The addition of ingredients without testing would be cited as an example of irresponsible conduct by the industry. Professor Daynard has been quoted as saying that the ingredients issue is a "bit disingenuous."

The paramount strategy for defendants in smoking and health cases is, of course, to keep the focus of the trial on the personal choices and responsibility of the plaintiff and away from the conduct of the industry. To the extent that plaintiffs succeed in diverting attention from the key defense issue by raising the ingredients issue, they will have sidetracked and weakened the defense effort. The defense should therefore make every effort to prevent plaintiffs from succeeding in utilizing the ingredient issue for diversionary purposes.

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If ingredients do become a trial issue, every effort must be made to convince the jury that they are a "side show," in that the plaintiff was aware of the risk allegations concerning cigarettes, chose to smoke, was not concerned with the source of the risk, and would have smoked even if he had known the specific flavorings and other ingredients added to the cigarettes.

Another important strategic objective in the litigation is to safeguard the confidentiality of the ingredients used in particular cigarettes. The ingredients are among the most closely-guarded trade secrets of the industry. All possible steps must be taken to protect the secrecy of that information from disclosure to outsiders, including co-defendants in the litigation.

II. SUBSTANTIVE POSITIONS

In responding to plaintiffs' claims regarding ingredients, the industry's substantive positions should be:

A. Causation -- There has been no scientific proof that any ingredient, as used in cigarettes, poses a health hazard to humans or increases the risk, if any, of cigarette smoking. The question of causation is a delicate one for both sides. If plaintiffs take the position that particular ingredients were causative agents, it weakens their attack on tobacco and may well serve to exculpate particular brands or styles. Up to the present, the plaintiffs have attempted to argue that all cigarettes are harmful. Defendants must argue

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that ingredients have not increased whatever risks, if any, are posed by cigarettes, thereby conceding that, if there is a risk, it is a risk presented by all cigarettes.

The ingredients issue potentially poses significant issues which go to the very heart of general causation. Both the industry and its critics have conducted the bulk of their research using "Kentucky Reference Cigarettes," supplied by the members of the industry. Although we have not yet obtained the precise formula for all of the Kentucky Reference Cigarettes, our present understanding is that few casing materials and no top dressings are added. (The cigarettes vary by tar and nicotine content, so it is probable that they contain the same residual amounts of processing agents as are found in commercial cigarettes, insofar as those agents are used to affect tar and nicotine content.)

If ingredients are claimed to be the "cause" of disease, then both the industry and its critics have tested the wrong product, and much of the prior research is flawed. Thus, both sides would be hard-pressed to rely on that research to support their respective positions on general causation. Plaintiffs could, however, continue to rely upon epidemiological research. On the other hand, in resisting plaintiffs' efforts to make ingredients an issue, the defense can rely upon the fact that critics of the industry have tested with Kentucky Reference Cigarettes, thereby implicitly conceding that tobacco, not additives, is the relevant product to test for causation. Dr. Gori's work, for example, implicitly supports this position.

Because some ingredients have been shown to be biologically active, defendants also have to qualify their arguments to the extent of stating that ingredients are not harmful "as used in cigarettes." The quantities of most flavoring ingredients used in top dressings are miniscule and therefore, according to our experts, pose little or no risk to human health. Although the casing materials and humectants are used in larger quantities, they, too, are thought to pose no significant risks to human health.[1]

Although the toxicologists consulted to date agree that ingredients do not increase the health risks of smoking cigarettes, it should also be noted that they also generally believe that tobacco is (at least) a risk factor in human disease.

The test data upon which toxicologists rely to determine the safety of ingredients does not support the same conclusion with respect to tobacco. If the consultants used to date are any guide, it seems unlikely that we will be able to locate a toxicologist who will give a "clean" opinion to tobacco, even if (s)he agrees that ingredients pose no risk. The most realistic hope is that we can get an opinion that tobacco is a "risk factor."

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1. There is at least one possible exception, glycerol, as to which a recent Japanese study suggests the possibility of this compound serving as a promoter. Toxicologists are not in accord on the significance or validity of this study, and further review is underway.

Although, as discussed below, the industry has not tested all ingredients as thoroughly as plaintiffs' experts may say is required, such tests as have been run generally indicate that ingredients do not increase the health risks of smoking cigarettes. The industry has dropped a number of ingredients over the years. Recently, a number of ingredients were dropped by the industry just prior to submitting the first annual list of ingredients to HHS, as required by the federal statute enacted in 1984. Although a few ingredients were dropped in earlier years because of the allegations concerning adverse health effects from use of those substances for applications different from cigarettes (e.g., coumarin), most were dropped either because of changes in formulations or because of feared "public relations" problems. The latter refer in some instances to substances with chemical names similar to allegedly harmful chemicals (e.g. dihydro-coumarin) which might cause confusion in the public's mind, even though the ingredient itself was harmless, as used in cigarettes. In other instances there were troublesome test phenomena which, while probably irrelevant under the conditions of cigarette usage, nonetheless seemed to pose unnecessary perception problems. Possible public relations problems were the stated reason for deletion of most of the ingredients prior to submitting the list to HHS. Plaintiffs may well, however, argue that the industry "purged" a group of harmful chemicals only after it was threatened with public disclosures. Certainly the "purged" ingredients are a target of opportunity for plaintiffs.

B. Design Defect -- Plaintiffs may attempt to argue that the addition of ingredients removes cigarettes from the "good tobacco" exception of Comment (i) to Restatement of Torts § 402A and potentially renders the industry liable for a design defect. The industry's position is that "good tobacco" has always been a combination of tobacco leaves, flavorings, and humectants. It is difficult (although possible) to produce cigarettes without some additional ingredients. The framers of Comment (i) undoubtedly meant to include within Comment (i) tobacco as it has historically been made and consumed. Thus, Comment (i) would exculpate "well-made" cigarettes utilizing ingredients, unless a plaintiff could show either: (A) that (i) the defendants' cigarettes differed from traditional cigarettes; (ii) that the difference materially increased the known risks of smoking cigarettes; and (iii) this difference caused plaintiff's disease; or (B) injury resulting from some impurity or adulteration in the ingredients (i.e., a so-called "manufacturing defect"). Exactly how these claims would be shaped will turn in large part on how a given jurisdiction treats consumer expectation and risk utility.

Unfortunately, there is no known "history" of Comment (i) which expressly validates the industry's position. There is, however, ample evidence of the historical use of ingredients in cigarettes--and before them, in pipe and chewing tobaccos--which should be persuasive as to the proper interpretation of Comment (i). For example, menthol cigarettes

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were well-established by the early 1950's. Moreover, Comment (i) itself suggests that the framers had ingredients in mind. In discussing liability for whiskey, the Comment states: "[B]ad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous." This language suggests that whiskey containing some level of fusel oil would be protected by Comment (i), even though fusel oil is an ingredient of whiskey other than ethyl alcohol.

C. Corporate Misconduct -- Plaintiffs will attempt to show that the industry used untested ingredients in disregard of the safety of consumers. While there is some evidence which could be marshalled in support of that argument, the industry does have strong positions which it could assert. As discussed above, however, rebutting a misconduct case is contrary to the overall strategic goal of focusing on plaintiffs' conduct and will, moreover, be difficult and complex.[2/] If necessary, rebuttal would consist of the following principal points:

(1) There is no scientific proof that ingredients pose a health hazard or increase the risk of cigarette smoking, as used in cigarettes. Standing alone, this "no harm -- no foul" defense may be sufficient to rebut causation but

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2. A corporate misconduct test premised upon ingredients would consist of claims of testing which was both belated and inadequate, failure to make adequate inquiry into the composition of flavors produced by outside flavor houses, and the failure to remove ingredients known or shown to be harmful.

provides little help on the principal issue for which plaintiffs hope to use ingredients, i.e., corporate misconduct. It is, nonetheless, an essential lynchpin to the defense.

(2) To the uninitiated, a list of the ingredients used in cigarettes will be surprising, intimidating, and possibly frightening. While some of the ingredients are familiar (e.g., cocoa, menthol), others have exotic chemical names. Part of a successful defense to the ingredients issue will be to educate the jury on the fact that most of the ingredients used in cigarettes are found widely in the human food chain, either as natural ingredients or as additives. Such an education, together with the use of common, rather than chemical, names and terms with connotations less pejorative than "additives," such as "flavorings" or "ingredients," should reduce the initial "shock value" of the ingredients list. Likewise, evidence can be developed establishing that a host of commonplace and benign substances have intimidating scientific names--thus Vitamin D becomes 1,25 dihydroxycholicalciferase.

(3) The industry had valid reasons for protecting the confidentiality of the ingredients used in particular brands. Even Congress recognized the legitimacy of the industry's claims of secrecy when it required that disclosure of ingredients be made on an industry-wide, rather than company or brand, basis. Moreover, the entire

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flavorings industry relies primarily on trade secrecy protection. Until recently, RJRT (and presumably other tobacco companies as well) was unable to persuade many flavor houses to disclose the components of the flavorings they sold to it.[3] Even after passage of the federal law requiring disclosure, many flavor houses would disclose only "masked" lists, which contained all ingredients actually used and extra ingredients that were not used. Many would not reveal the proportions in which the ingredients were used and instead would disclose only the maximum levels of ingredients.

(4) Although the industry has kept the actual ingredients secret, it has never disguised the fact that cigarettes do contain ingredients other than tobacco and paper. Several old advertising campaigns were based upon the claimed superiority of the ingredients in a particular brand. RJRT's REAL brand, which was marketed from 1977-80,

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3. Obviously, the industry cannot use the fact that it was unaware of the components of flavorings as a defense, because it continued to utilize those flavorings. The extreme secrecy of the flavor houses does, however, support the legitimacy of the industry's claims of trade secret protection for the ingredients in individual brands. (It also appears that food companies often use flavorants the ingredients of which they don't know.) It should also be noted that the need to safeguard the flavor formula for particular brands supports the industry's position that cigarettes are more than fungible nicotine delivery systems and that smokers discern and regard as important the taste differences among brands and thus smoke for reasons other than the effects of nicotine.

was distinguished on the basis of its "natural" ingredients, as opposed to the "artificial" flavor enhancers found in "all major brands." Similarly, PM's ads for Merit refer to the brand's "enhanced flavor". The 1972 book by Leffingwell, et al., Tobacco Flavorings For Smoking Products, contained an extensive listing of ingredients, including most, if not all of those then used by RJRT, and the authors acknowledged the Company's cooperation. In addition, the time line on additive awareness has thus far identified published discussion of cigarette ingredients dating back to a 1953 article in Consumer Reports.

(5) The food industry also guards the secrecy of its ingredients. Most flavorings are used in sufficiently small quantities that disclosure is not required. Rather, they are disclosed on food and beverage labels as "Spices; Natural and Artificial Flavors." If cigarettes were subject to the FDA disclosure rules applicable to food, some casing materials and humectants might have to be disclosed individually, but most, if not all, of the flavoring ingredients would be disclosed under the general category of "Natural and Artificial Flavors," because of their miniscule proportions.

(6) Plaintiffs' toxicologists may claim that the industry's testing of additives has not been adequate. There are a number of explanations for the testing which has occurred -- none of which is entirely satisfactory or alone sufficient.

In the first place, the toxicological examination of the safety of ingested substances is of relatively recent vintage, and the standards, and the meaning of the results (if any) are constantly evolving. It was not until 1958 that the so-called "Delaney Amendment" to the Federal Food and Drug Act was passed. The Delaney Amendment bans the addition to food of substances known to cause cancer in man or animals. The Ames test for biological activity was not published until the 1960's, and it was not generally accepted for use until well into the '70's. The National Toxicological Program, which attempts to identify carcinogenic substances, is of relatively recent vintage, and analysis of many commonly-used substances is still in process. Chronic studies didn't become commonplace until the mid '70's.

Not only are regulatory initiatives of relatively recent vintage, but there has been, and continues to be, considerable debate as to the proper methodology by which to test particular substances, whether particular substances should be tested, and what results will establish safety with an acceptable degree of certainty. Those issues are presented by cigarette ingredients, which are used in miniscule amounts, combined with numerous other ingredients, pyrolized, and consumed by inhalation.

The policies followed by RJRT have been compiled separately. Some of the more important are discussed below.

(a) Many ingredients used by American cigarette manufacturers are approved for use in foods under the "GRAS" ("Generally Recognized As Safe") standards of the Flavor and Extract Manufacturers' Association ("FEMA") or the FDA. The GRAS standards of FEMA are subjective and frequently rely on a long history of usage without reported problems. The GRAS standards are of limited utility, in that a long history of safe usage cannot be established for cigarettes and safe usage in foods does not automatically translate into safe usage when the ingredients is pyrolized and inhaled.

(b) Many of the ingredients used by American cigarette manufacturers have also been approved for use by the scientific bodies established to promulgate approved ingredients for cigarettes sold in West Germany and the U.K. Inclusion of an ingredient on those lists, both of which are of fairly recent vintage, does provide some comfort to American manufacturers. The lists also raise the issue of why American manufacturers have not undertaken a

similar cooperative effort to validate their use of ingredients.[4]

(c) RJRT has monitored the scientific literature concerning ingredients. Although helpful, literature review is of somewhat limited utility, in that many ingredients have not been tested either as pyrolytes or through the inhalation route.

(d) Since at least 1977, RJRT's policy was not to utilize ingredients which contributed "strangers" to cigarette smoke. That policy was based on the common sense notion that, if an ingredient contributes nothing new to the smoke, there is little reason to test it. Many of the flavorings used in top dressings are volatile and "boil off" into the smoke without being pyrolized, although the data on this is scanty. Other ingredients, particularly humectants and casing materials, are pryolized, and the by-products appear in the smoke.[5]

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4. There have been proposals from time to time for industry-wide ingredient evaluation. One such is under consideration at present. There is some evidence from which a plaintiff could argue that products liability concerns have prevented co-operative testing.

5. As noted above, the "Kentucky Reference Cigarette" used in most scientific experiments contains the humectant glycerol, and possibly some residual processing agents, but the exact formula of those cigarettes is not yet known.

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(7) It should also be noted that the various available methods for testing ingredients are expensive, involve some difficult technical and design problems, and generally do not lead to definitive conclusions. Ames tests and other tests for genetic toxicity are relatively inexpensive but are not generally regarded as definitive predictors of effects on humans. Skin painting tests are viewed as more definitive by some scientists but not by others, including the tobacco industry. Skin painting tests on any particular ingredient would be more expensive than an Ames test but less expensive than inhalation tests.[6] Inhalation tests are expensive and time-consuming. Inhalation tests for toxicity generally require either 14 or 90 days. Testing for carcinogenicity in animals usually requires a "2-Year" study. A "2-Year" inhalation study would take about 5 years to complete[7] and cost $4-5 million. Moreover, even that test yields only probabilities of safety, because of the

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6. Skin painting tests cannot, however, be used to test those ingredients which boil off prior to pyrolysis, because those vapors are not trapped in the "tar" collected by the common methods of collecting tar.

7. The animals are exposed to the tested substance for 2 years and then killed. Thereafter their tissues are subjected to a large battery of examinations and tests. The latter steps, as well as compilation and analysis of the data, account for much of the time and expense.

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imprecision inherent in an effort to extrapolate from animals to man.[8]

One basis for the industry's "Open Question" position on general causation is the fact that inhalation of whole smoke does not produce lung tumors analogous to human cancers in animals, although other substances do. Animals exposed to whole smoke have experienced tissue changes, but those changes are not deemed to be significant, insofar as carcinogenisis is concerned. If ingredients were subjected to inhalation testing, some animals would be exposed to smoke from cigarettes without the ingredients, and others would be exposed to smoke from cigarettes made with varying proportions of the ingredient. The experiment would be designed to determine whether any dose-related changes in biological activity are noted, thereby attributing some significance to the tissue changes.

The use of inhalation tests for ingredients can be reconciled with the industry's reliance on whole smoke tests in the following way. The whole smoke inhalation data casts

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8. According to Drs. Suber and Appleton of RJRT, of the thousands of animal carcinogens identified to date, only about 25 chemicals are known to have the same effects on humans. The low level of correlation may be the result of metabolic or other changes induced solely by the large doses used in experiments, which are frequently set at levels just low enough to permit the animal to survive for the duration of the test. Many toxicologists argue that the mega-dose methodology is inherently flawed. At present, that methodology is, however, "accepted" by general concensus as the best available alternative.

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doubt on the theory that cigarettes cause lung cancer; it does not resolve that "Open Question" entirely or eliminate cigarettes as a risk factor. If the addition of a certain ingredient does not increase the level of biological activity caused by whole smoke, it has not increased whatever risks may be posed by cigarettes. Conversely, a significant, dose-related change in biological activity caused by a particular ingredient may indicate an increase in the risk that similar activity will be experienced in humans. Thus, without conceding that tissue changes short of malignancy are indicators of carcinogenic properties, such changes may indicate increased levels of risk.

Although the costs and inherent uncertainties of testing are obviously not a complete defense to why ingredients have not been tested, the fact is that the industry for many years chose to concentrate its research efforts on identifying the constituents of smoke and determining whether such constituents could be a cause of adverse health effects, rather than on determining whether particular ingredients (which did not contribute "strangers" to smoke) had such effects. Most scientists would probably agree that that choice was a wise one. Properly developed, juries should come to understand that there are no bright-line tests that say "safe" or "unsafe," and that much of their faith in the certainty of science is misplaced--which is why industry scientists have been

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justified in relying on common sense (i.e., the de minimus quantities in which so many ingredients are used) and long experience to guide their research.

III. TACTICS

The strategic and substantive considerations discussed above dictate that the defense take all steps necessary to limit both the disclosure of information regarding ingredients and the involvement of ingredients issues in the litigation.

To that end, the primary defense posture should be to resist disclosure of ingredients information requested in discovery on grounds of relevance. The industry's position is that the constituents of smoke are the relevant inquiry, because it is those compounds, not the ingredients of cigarettes, which plaintiff necessarily claims to have caused his disease. RJRT is prepared to disclose a list of smoke constituents.

If the court does require disclosure of some ingredients in discovery, despite all efforts to resist such a ruling, the defense should take the following steps:

1. Consistent with the position taken on other issues, such as advertising, disclosure of ingredients should be limited to only the brands which plaintiff smoked and the years during which (s)he smoked them.

2. Disclosure should be limited to only the ingredients list.[9] The list should be accompanied with a set of contention interrogatories, seeking to have plaintiff commit to a position on:

(a) whether (s)he claims tobacco is the cause of the disease;

(b) what role (s)he claims tobacco played in causing the disease;

(c) whether (s)he claims any particular ingredient played a role in causing the disease and, if so:

(i) which ingredient;

(ii) what role (s)he claims it played; and

(iii) identification of an expert who holds the opinion that the ingredient played a role in plaintiff's disease.

3. Entry of a protective order seeking protection of the ingredient list by strictly limiting disclosure to plaintiff's counsel and designated expert. Only if plaintiff's expert identifies particular ingredients which (s)he claims to

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9. Consideration has been given to forcing plaintiffs to compile a list of ingredients from available records, pursuant to F.R.C.P. 33(c). Those plaintiffs for whom the ingredients issue is a diversionary tactic may not wish to assume the costs and burdens of compiling such a list. In the case of RJRT, however, the extreme difficulty of compiling a list from the available records--due to their complexity, rather than any unavailability--suggests that a Rule 33(c) response may not be available. Moreover, unwarranted reliance on Rule 33(c) may lead the Court to conclude that defendants are being obstructionists and, thus, lead to denial of the important protections which the industry needs.

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have contributed to plaintiff's disease would discovery beyond identification of the ingredient be permitted. A draft protective order embodying these concepts is attached.

4. Where available, filing a motion for partial summary judgment or a motion in limine arguing that Comment (i) forecloses strict liability for cigarettes or their ingredients, unless plaintiff can show that the defendants' cigarettes were different from traditional cigarettes and that the difference was sufficiently material to have caused plaintiff's disease (i.e., that defendants' cigarettes posed risks which were materially greater than those risks generally known to be posed by cigarettes).

5. Filing a motion in limine seeking to eliminate the ingredients issue altogether on grounds of relevance and prejudice outweighing probative value. See Fed. R. Ev. 403. Alternatively, the motion would seek to limit the litigation to only those ingredients which plaintiffs' experts claim to have contributed to the plaintiffs' disease.

The extent to which plaintiff successfully resists the defendants' efforts to limit the involvement of ingredients issues at trial will dictate how much effort must be devoted to presentation of the industry's position at trial. Although, as discussed above, ingredients are essentially a "plaintiff's issue", the issue involves too much potential prejudice to ignore it altogether. If a plaintiff is given "free rein" to raise the ingredients issue and weave it into a "corporate

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misconduct" case, the defense has little choice but to respond with the defenses set out above.

If a defendant knows, through pre-trial developments, that the plaintiff will use ingredients solely as an emotional, corporate misconduct issue, unrelated to any evidence that one or more ingredients actually contributed to the plaintiff's condition, a bold defusing may serve well: inform the jury in opening statement (especially if the plaintiff has raised ingredients in his opening) that it won't hear any such evidence, and that reference to ingredients is simply a demonstration of the irresponsible lengths to which the plaintiff is prepared to go. Assuming this prediction is borne out, the point can be revisited in closing, perhaps with telling effect.

With respect to trial testimony by an expert, the defense has two choices. In the first scenario, a toxicologist would testify that the "risk" to health, if any, is posed by the constituents of tobacco smoke and that ingredients generally are a "non-issue" because their miniscule quantity means that they would have no perceptible effect on smoke chemistry or on human health. The second approach would be to defend each particular ingredient on the basis of existing research. The second alternative would seem to be more feasible if plaintiff has focused on a selected group of additives than if the witness would be forced to defend hundreds of different compounds. The witness will also have to undertake to educate the jury as to the ubiquity and benignity of flavorants in modern society.

However the plaintiff chooses to use the ingredients issue, we must be prepared to "de-mystify" it." Research and actual jury experience indicate that ingredients, with their intimidating and alien names, alarm laymen without any rational basis. The jurors must be taught, therefore, often from opening statement on, that they live in a world of ingested chemicals--chemicals which are found in the food supply both naturally and as additives--and that the only thing remarkable about their use in cigarettes is their relatively low rate of application.

One way to do this will be through the use of examples. A toxicologist, for example, may take a prosaic and "wholesome" product, such as a Hershey Bar, and expalin what it consists of: thousands of sinister-sounding chemicals, many occurring naturally in chocolate, some of which are biologically active, many of which are used in cigarettes, and all of which the FDA has approved from human consumption.[10] A variation would be "a day in your life"--an explanation of the chemicals we consume and inhale every day, from morning to night. In either case, the objective should be to leave the jurors with an

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10. The parallel is imperfect, of course--we don't inhale the vapors of a burning Hershey Bar. Plaintiffs may argue that pyrolosis is the critical difference and, as noted above, our pyrolitic data is sketchy in some areas. Our toxicologist must be prepared to opine whether pyrolosis should make any difference. The gap may be at least partially bridged by using a cooked food as an example--a cake mix, for instance. Charcoal broiling is another.

appreciation of the fact that chemicals are an inescapable fact of life, not an unanticipated assault on the uninformed smoker.

Another point worth arguing is that many goods, especially foods, pose the risk and the reward simultaneously and inseparably. Water slakes thirst as well as Coke, and with less risk. Likewise, to the extent ingredients do increase smoking risk--an untenable position--they are frequently the means by which low tar or nicotine cigarettes are rendered acceptable substitutes for high tar, high nicotine alternatives which many people believe pose greater risk.

Although this discussion has focused on cigarette ingredients, the analysis applies generally to all of the chemicals used in the manufacture of cigarettes--filter additives, paper additives, inks, glues, pesticides, freon and ammonia, for example. Because we cannot anticipate whether some or all of these will become the focus of litigation, we are assembling data about all of them, and our detailed evidentiary outline will be shaped to treat any or all of these substances.

John Edwards
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